NOV - 2 2000

K003131

SUMMARY OF SAFETY AND EFFECTIVENESS

Sponsor: Biomet Inc.
Airport Industrial Park
P.O. Box 587
Warsaw, IN 46581-0587

Contact Person: Carol Lauster

Device(s): pin, fixation, threaded

Classification: Class II

Device Product Code: 87 JDW (21 CFR 888.3690)

Intended Use: Stabilization of open and/or unstable fractures and where soft tissue injury may preclude the use of other fracture treatments such as IM rodding, casting, and other means of internal fixation.

Device Description: The self-drilling/self-tapping pins are designed in two sizes, 3mm and 4mm, corresponding to the major diameter of the thread. Both pins have a 4mm shank. At the end of the pin opposite the thread there is a tri-shank (three flats equally spaced) that is used as a driver for the pins.

Potential Risks: The potential risks associated with this device are the same as with any joint replacement device. These include, but are not limited to:

Nonunion or delayed union which may lead to breakage of the implant
Bending or fracture of the implant
Loosening or migration of the implant
Metal sensitivity, or allergic reaction to a foreign body
Decrease in bone density due to stress shielding
Pain, discomfort, or abnormal sensation due to the presence of the device
Nerve damage due to surgical trauma
Necrosis of bone
Postoperative bone fracture and pain
Inadequate healing

Predicate Devices: Radiolucent Colles Fracture Kit, 510(k)001760

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 2 2000

Ms. Carol Lauster
Regulatory Specialist
Biomet, Inc.
P.O. Box 587
Warsaw, Indiana 46581-0587

Re: K003131
Trade Name: Radiolucent Colles Fracture Kit
Regulatory Class: II
Product Code: JDW and LXT
Dated: October 5, 2000
Received: October 6, 2000

Dear Ms. Lauster:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): _____
Device Name: Self-drilling/self-tapping pins
Indications for Use:

Stabilization of open and/or unstable fractures and where soft tissue injury may preclude the use of other fracture treatments such as IM rodding, casting, and other means of internal fixation.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K003131